K020871

MAR 2 9 2002

510(k) SUMMARY

VITEK® 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nancy Weaver, Staff Regulatory/Clinical Affairs Specialist
Phone Number:	314-731-8695
Fax Number:	314-731-8689
Date of Preparation:	November 19, 2001

B. Device Name: VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin

Trade Name:	VITEK® 2 Levofloxacin
Common Name:	Levofloxacin (LEV)
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645

C. Predicate Device: VITEK ® 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Trimethoprim/Sulfamethoxazole (N50510/S139)

D. 510(k) Summary:

The VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin is intended for use with the VITEK® 2 System in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae* to antimicrobial agents. The antimicrobial presented in the VITEK® 2 AST panel is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The AST panels are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) my microdilution methodology.

The VITEK 2 system automatically fills the AST panels with a standardized organism suspension. The organism suspension may either be prepared automatically by the VITEK 2 or prepared manually. The filled AST panels are automatically sealed and loaded into the optical reader/incubator. Temperature is monitored and controlled throughout the incubation cycle. Organism growth in the test panel is continually monitored by the optical system. Optical readings are transformed by the VITEK 2

System into antimicrobial MIC's and category (**S**ensitive/**I**ntermediate/**R**esistant) interpretations.

The VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document ""Guidance on Review Criteria for Assessment of Antimicrobial susceptibility Devices", dated March 8, 2000. The Premarket Notification (510[k]) presents data in support of the VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin.

An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of the VITEK 2 AST Panel by comparing its performance with an NCCLS frozen reference panel. Challenge strains were compared to an "Expected Result". The VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin demonstrated acceptable performance of 99.8% overall Essential Agreement with automatic dilution when compared to the frozen reference panel.

Reproducibility testing demonstrated acceptable reproducibility with both automatic and manual dilution methods.

Quality Control demonstrated acceptable results for VITEK 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Nancy Weaver
Staff Regulatory/Clinical Affairs Specialist
bioMerieux, Inc.
595 Anglum Road,
Hazelwood, Missouri 63042-2320

MAR 2 9 2002

Re: k020871
Trade/Device Name: VITEK® 2 Gram Positive Antimicrobial Susceptibility Test Panel for *Streptococcus pneumoniae*: Levofloxacin
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: November 19, 2001
Received: December 28, 2001

Dear Ms. Weaver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 020871

Device Name: VITEK® 2 Gram Positive AST Panel for *Streptococcus pneumoniae*: Levofloxacin

Indications for Use:

The VITEK® 2 Gram Positive AST Panel for Streptococcus pneumoniae: Levofloxacin is intended for use with the VITEK® 2 System in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae* to antimicrobial agents. The antimicrobial panel presented in the VITEK® 2 AST card is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Prescription Use X

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020871